



MITT ROMNEY
GOVERNOR

KERRY HEALEY
LIEUTENANT GOVERNOR

TIMOTHY R. MURPHY
SECRETARY

PAUL J. COTE, JR.
COMMISSIONER

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Center for Quality Assurance and Control
99 Chauncy Street, 2nd Floor
Boston, MA 02111
617-753-8000

**Community Hospital Application for Special Project
Approval to Participate in the MASS COMM Trial**

PLEASE PRINT

_____, located at _____
Hospital Name

through the submission of this completed application requests special project approval under Massachusetts hospital licensure regulation 105 CMR 130.051 Special Projects, to participate in the MASS COMM Trial to study the safety and efficacy of percutaneous coronary interventions (PCIs) performed at community hospitals without surgery-on-site compared to PCIs performed at tertiary hospitals with surgery-on-site.

**Community Hospital
Principal Physician
Investigator:**

First Name Last Name

Phone Fax Email

Principal Nurse:

First Name Last Name

Phone Fax Email

Data Coordinator:

First Name Last Name

Phone Fax Email

Participating Interventionalists at this hospital:

Corresponding Surgery-on-Site (SOS) Hospital(s):

Check as applicable:

- ☐ The hospital provides primary angioplasty **24 hours per day, seven days per week (24/7)**.
- ☐ The hospital does not currently provide primary angioplasty **24 hours per day, seven days per week**. Primary angioplasty is available (insert days and hours of availability):

_____.
Primary angioplasty will be available 24/7 beginning (insert date):_____.
- ☐ The hospital attests that the each interventionalist participating in the trial at this site:
- is board certified in interventional cardiology,
 - is credentialed at the corresponding surgery-on-site hospital(s),
 - has performed 75 PCI procedures in the past year, and
 - will continue to perform 75 PCI procedures per year.
- ☐ The hospital attests to the IRB's approval of participation in the MASS COMM Trial.
- ☐ The hospital attests to the IRB's approval of the informed consent document for the MASS COMM Trial.
- ☐ The hospital agrees to pay all costs associated with the MASS COMM Trial, as determined by the Principal and Co-Principal Investigators.
- ☐ The hospital has a signed Memorandum of Understanding with Harvard Clinical Research Institute (HCRI) regarding the MASS COMM Trial.
- ☐ The hospital has a signed agreement with each of the corresponding SOS hospitals listed

above that addresses responsibilities to ensure management of complications experienced by any elective angioplasty patient during his/her hospital stay; transport and/or scheduling of patients randomized to the SOS hospital; rapid transport for patients in whom a procedural complication warrants surgical intervention; and maintenance by the SOS hospital of a contract with HCRI. A copy of each agreement is enclosed with this application.

- ☐ The hospital agrees to submit all data requested by HCRI, MASS-DAC Data Coordinating Center and the Department of Public Health in a timely manner and consistent with all timeframes identified in the MASS COMM Trial protocol.
- ☐ The hospital attests that no patient shall be enrolled in the MASS COMM Trial prior to:
 - the hospital's receipt of written approval to participate from the Department of Public Health,
 - the establishment of signed contracts for the hospital and its partnering/corresponding surgery-on-site hospital(s) with HCRI, and
 - receipt of final written authorization from HCRI to proceed with patient enrollment.
- ☐ The hospital attests that it will continue to collect and submit the data required for participation in the Department's *primary angioplasty* special project.

Signatures:

Chief Executive Officer:

Print name

Signature Date

Chief of Cardiology or Cardiovascular Services:

Print name

Signature Date

Community Hospital Principal Physician Investigator:

Print name

Signature Date

Return the completed, signed application to:

Nancy Murphy
Division of Health Care Quality
99 Chauncy Street, 2nd fl.
Boston, MA 02111